

Dupixent[®] (dupilumab) – New indication

- On September 28, 2022, [Sanofi](#) and [Regeneron](#) announced the [FDA approval](#) of [Dupixent \(dupilumab\)](#), for the treatment of adult patients with prurigo nodularis.
- Dupixent is also approved for the treatment of atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis, and eosinophilic esophagitis.
- Prurigo nodularis is a chronic, debilitating skin disease with underlying type 2 inflammation. People with prurigo nodularis experience intense, persistent itch with thick skin lesions that can cover most of the body.
 - There are about 75,000 adults in the U.S. living with prurigo nodularis.
- Dupixent is the first approved treatment for prurigo nodularis.
- The approval of Dupixent for the new indication was based on two randomized, double-blind, placebo-controlled studies (PRIME and PRIME 2) in 311 adult patients with prurigo nodularis. Patients received Dupixent or placebo. Efficacy was assessed with the proportion of patients with improvement (reduction) in Worst Itch-Numeric Rating Scale (WI-NRS) by ≥ 4 points, the proportion of patients with Investigator's Global Assessment for Prurigo Nodularis-Stage (IGA PN-S) 0 or 1 (the equivalent of 0 to 5 nodules), and the proportion of patients who achieved a response in both WI-NRS and IGA PN-S per the criteria described.
 - In PRIME, the proportion of patients who met both the W-INRS and IGA PN-S endpoints at week 24 was 38.7% with Dupixent vs. 9.2% with placebo (treatment difference 29.6, 95% CI: 16.4, 42.8).
 - In PRIME 2, the proportion of patients who met both the W-INRS and IGA PN-S endpoints at week 24 was 32.1% with Dupixent vs. 8.5% with placebo (treatment difference 25.5, 95% CI: 13.1, 37.9).
- The most common adverse reactions ($\geq 2\%$) with Dupixent use for prurigo nodularis were nasopharyngitis, conjunctivitis, herpes infection, dizziness, myalgia, and diarrhea.
- The recommended dose of Dupixent for the treatment of prurigo nodularis is an initial dose of 600 mg (two 300 mg subcutaneous injections) followed by 300 mg given every other week.
 - Refer to the Dupixent drug label for dosing for all its other indications.